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In re Application of:	VARRIANO-MARSTON, Elizabeth	Group Art Unit: 1772
Serial No.	09/877,757	Examiner: Patterson, Marc
Filed:	06/08/2001	Atty. Dkt. No: MARS93-DIV

For: REGISTERED MICROPERFORATED FILMS FOR MODIFIED/CONTROLLED ATMOSPHERE PACKAGING

To: Mail Stop AF
Commissioner for Patents
PO Box 1450
Alexandria, VA 22313-1450

From: 24222

OFFICIAL

Dear Honorable Commissioner:

This declaration is offered in support of the above application for patent.

RULE 132 DECLARATION OF ELIZABETH VARRIANO-MARSTON (37 CFR 1.132)

This Declaration is submitted following a Personal Interview on July 29, 2004, attended by Patent Examiner Marc Patterson, Attorney Scott Asmus and the under signed Inventor, Elizabeth Marston. My background and experience in the field has already been described in the Declaration dated Oct. 18, 2002 and is incorporated by reference herein.

During the Interview, I described the distinctions between the present invention and the Greengrass patent. As an expert in microperforation technology, Greengrass could not control the atmosphere at optimum conditions inside retail packages (weighing 10 lbs or less) of produce using the examples that they describe in their patent due to the extremely large size holes described therein. The hole size and number of holes is directly related to the O_2 flux noted in Claim 1 which is, of course, related to controlling and maintaining the atmosphere in the package. As detailed herein, it is not possible to establish the claimed flow rate nor the atmospheric conditions in the packaging as set forth in the present invention using the Greengrass hole size/number of holes.

For example, Greengrass describes on column 3, line 7, "[w]hen micro perforation pattern, utilizing the arrangement no. of lines/distance lines apart (mm)/pitch of pins (mm)/ size of holes (mm) 05/20/30/60 was used on PVC stretch film overwrapped punnets, not only was the weight loss of the mushrooms significantly reduced, the mushrooms would keep for periods of up to six days longer than spiked packs before going brown."

Using the above example from Greengrass, I have calculated the flux rates required to maintain an optimum atmosphere inside a package of whole mushrooms. Since Greengrass does not indicate what weights of produce they tested, I selected a weight of 40 oz (1.135 kg) whole mushrooms. Equations (1), (2), and (3) below (from the present application) is used to determine the total O_2 Flux ($Flux_{O2\text{-}Total}$) requirements of a fresh produce package, including the O_2 Flux of the breathable area of the packaging film ($Flux_{O2\text{-}film}$), and the O_2 Flux of the microperforations ($Flux_{O2\text{-}MP}$), required to maintain a desired atmosphere inside a package containing a specific fresh fruit, fresh vegetable, fresh herb or fresh flower.

(1) $OTR_T = [(M \times RR) \ / \ (A_S\, P\, (0.21 - IntO_2))] \times 24$ hrs/day

where,

OTR_T = total OTR required for the package in cc O_2 / m^2-day-atm

M = mass of produce (kg)

RR = respiration rate (cc O_2/kg/hr) @ the expected storage temperature

A_S = breathable surface area of the package (m^2)

P = atmospheric pressure (atm), assumed to be 1

Int O_2 = desired O_2 atmosphere inside the package stated as a volume fraction (i.e., if the desired O_2 is 8%, the volume fraction is 0.08).

For the Greengass example, to establish an optimum atmosphere of 3% O_2 and 10% CO_2 at 5° C (see Postharvest Produce Fact Sheet, attached) inside a tray containing 1.135 kg of whole mushrooms and overwrapped with microperforated PVC film, with dimensions of 34.29 cm wide x 48.22 cm long x 25 micron thick ($OTR_{base\text{-}film}$ = 13,330 cc/m^2-day-atm – see Table 2 Properties

from the Wiley Encyclopedia of Packaging Technology, attached), with an O_2 respiration rate of 35 cc/kg/hr, the OTR_T required by the package would be:

$$OTR_T = [(1.135 \text{ kg} \times 35 \text{ cc/kg/hr}) / ((0.3429 \text{ m} \times 0.4822 \text{ m})) \times 1 \text{ atm} (0.21 - 0.03)] \times 24 \text{ hr/day}$$

$$= \mathbf{32{,}034} \text{ cc/m}^2\text{-day-atm}$$

Once the OTR_T requirements for a particular item and package size are determined from equation (1), then the O_2 flow through the breathable surface area of the bag per day ($Flux_{O2\text{-film}}$ in cc/day-atm), is calculated using equation (2):

$$(2) \quad Flux_{O2\text{-film}} \text{ (cc/day-atm)} = OTR_{base\text{-film}} \text{ (cc/m}^2\text{-day-atm)} \times A_S \text{ (m}^2\text{)}$$

In our example, the dimensions of the breathable area of a PVC film used to package 1.135 kg of whole mushrooms are 34.29 cm x 48.22 cm, and the OTR of the base PVC film is 13,300 cc/m^2-day-atmosphere. The $Flux_{O2\text{-film}}$ (cc/day-atm) through the breathable area of the package is:

$$Flux_{O2\text{-film}} \text{ (cc/day-atm)} = (13{,}300 \text{ cc/m}^2\text{-day-atm}) \times 0.1653 \text{ m}^2$$

$$= \mathbf{2{,}198} \text{ cc/day-atm}$$

However, a total $Flux_{O2\text{-Total}}$ of **5295** cc/day-atm is needed for this package as shown below:

$$Flux_{O2\text{-total}} = OTR_T \text{ cc/m}^2\text{-day-atm} \times A_s \text{ (m}^2\text{)}$$

$$Flux_{O2\text{-total}} = 32{,}034 \text{ cc/m}^2\text{-day-atm} \times 0.1653 \text{ m}^2 = \mathbf{5295} \text{ cc/day-atm}$$

Therefore, the majority of $Flux_{O2\text{-Total}}$ must be supplied by the microperforations ($Flux_{O2\text{-MP}}$):

$$(3) \ Flux_{O2\text{-MP}} = Flux_{O2\text{-Total}} - Flux_{O2\text{-film}}$$

$$= 5295 \text{ cc/day-atm} - 2{,}198 \text{ cc/day-atm} = \mathbf{3097 \text{ cc/day-atm}}$$

According to the present patent application, the number of 150 micron (longest diameter) perforations required in the PVC film that overwraps 1.135 kg mushrooms is equal to:

(3097 cc/day-atm) / (200cc/day-atm per Type II microperforation) = 15 microperforations

For illustrative purposes, one only needs to look at the total open area provided by the microperforations to show how different the Greengrass patent is in relation to the present invention. In the present invention, a total open area for one, 150-micron microperforation, assuming a circular hole, equates to:

$$A = \pi r^2 = 3.14 \times (150/2 \text{ micron})^2 = 17{,}662.5 \text{ micron}^2$$

And, the total open area for the 15, 150-micron microperforations, calculated above, assuming circular holes, would be:

$$A = 15 \times 17{,}662.5 \text{ micron}^2 = 264{,}938 \text{ micron}^2$$

It should be noted that while it may not be readily apparent, employing a single large hole instead of a number of smaller microperforations does not accomplish the desired performance and may also introduce problems with debris and contaminants. That is why the number and size as well as the flow rates are presented in the claims. This is for illustrative purposes to more readily show the extraordinary difference between the Greengrass patent and the present invention.

Greengrass recommends for fresh mushrooms in column 3, line 7-10, " . . . micro perforation pattern, utilizing the arrangement no. of lines/distance lines apart (mm)/pitch of pins (mm)/ size of holes (mm) 05/20/30/60 was used on PVC stretch film overwrapped punnets . . ."

This arrangement indicates that they are using 5 lines (rows) of perforation with the perforations being 60 mm in diameter. A 60 mm perforation is 60,000 microns. That means that each of the Greengrass perforations of 60,000 microns is 545 times larger than the smallest microperforation

size claimed in the present invention, and **150** times larger than the largest microperforation size taught by the present invention.

The total open area of one, 60,000-micron hole for Greengrass, assuming a circular hole, equates to:

$$A = \pi r^2 = 3.14 \times (60{,}000/2 \text{ micron})^2 = 2{,}826{,}000{,}000 \text{ micron}^2$$

As illustrated – the total open area for Greengrass of 2,826,000,000 micron^2 is significantly larger than the 17,662.5 micron^2 open area for one, 150-micron hole of the present invention and also significantly larger than the 264,938 micron^2 open area for 15, 150-micron holes !

Since the flux of a 150-micron hole is 200cc/day-atm, then one of Greengrass's 60,000-micron perforations in the mushroom package would have an O_2 flux of 80,000 cc/day-atm. However, a $Flux_{O2\text{-}MP}$ of 3097 cc/day-atm (see equation 3 above) is only required for the mushroom package, so the Greengrass patent cannot be used to control the optimum atmosphere in the mushroom package at the UC Davis recommended values of 3% O_2 and 10% CO_2.

Greengrass recommendation for mushroom PVC overwrap film is 5 rows of 60,000-micron perforations. Greengrass does not specify how many holes are in each row, but as the calculations demonstrate above, just **<u>one</u>** Greengrass 60,000 micron hole is too large to control the atmosphere at recommended levels – so multiple holes of 60,000 microns clearly will not work according to the present claimed invention

The smallest hole size described in one of the embodiments and claimed by Greengrass is 20 mm (i.e., 20,000 microns) which would produce an O_2 flux of 26,667 cc/day-atm. Again, <u>one,</u> 20,000 micron hole has **8.6** times more O_2 flux than the 3097 cc/day-atm flux required for this mushroom package – so it also cannot function as taught and claimed by the present invention.

Thus, Greengrass does not describe or infer a packaging material that is capable of functioning according to the claimed invention. It simply will not work.

Greengrass also states that the size/number of holes is easily derived by 'scientific testing.' As one skilled in the art, and with 21 years of research experience in the fresh produce packaging industry, deriving the size and number of microperforations needed for each produce type, variety, weight, cut size, and storage temperature is a daunting task. One skilled in the art cannot readily derive the size and number of microperforations for the optimal packaging atmosphere via empirical testing without excessive and undue experimentation. Furthermore, as the teaching of Greengrass is not capable of producing the optimum atmospheric conditions within the claimed range – it obviously is not easily derived by scientific testing.

It should also be noted that Greengrass describes "controlling ripening." Not all produce ripens, but all produce does respire. Ripening is a separate metabolic process that occurs with ripening fruits; most vegetables do not ripen.

The goal in fresh fruit and vegetable packaging is to use MAP/CAP to preserve produce quality by reducing the aerobic respiration rate but avoiding anaerobic processes that lead to adverse changes in texture, flavor, and aroma, as well as an increased public health concern. Aerobic respiration can be defined by the following equation:

$$(CH_2O)n + nO_2 \rightarrow nCO_2 + nH_2O + \text{heat}$$

where O_2 from the air is used to metabolize carbohydrate ($(CH_2O)n$) reserves and in the process, CO_2, and H_2O are produced and heat is generated. Since respiration rates (not ripening as mentioned by Greengrass) must be matched to film gas transmission requirements, the number of variables that would have to be considered in a scientific study of just one produce item at just one weight would be as follows: base film composition and OTR , hole size, hole number, and O_2 flux of each hole size, respiration rate of the produce, age of the produce, contribution of microbial contaminants to respiration rates, temperature of storage, and storage time.

In addition, a reliable and reproducible method of producing hole sizes in the size range that I am claiming is difficult to accomplish without sophisticated, non-mechanical perforating technology. Obviously, Greengrass did not scientifically determine the size and number of holes required by

mushrooms or the other produce items they mention in their patent since Greegrass hole sizes are too large to effectively control the atmosphere inside fresh produce retail packages. The laser hole drilling system of the present invention produces consistent hole sizes in the registered target area for the packaging materials of my invention. Greengrass punches very large holes throughout PVC film, many of which may be wholly or partially occluded by produce within the package.

The packaging material according to the claimed invention is clearly distinguished from Greengrass and the other references. The hole sizes of Greengrass cannot function according to the parameters of the claims and the Greengrass holes are not in a registered target area.

The undersigned declares that all statements of his own knowledge made herein are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application of any patent issuing thereon.

Respectfully submitted,

Elizabeth Varriano-Marston

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Mushroom

Recommendations for Maintaining Postharvest Quality

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Maturity Indices

Agaricus bisporus mushrooms (Button Mushrooms) are harvested by maturity and not by size. Maturity is reached when the caps are well-rounded and the partial veil is completely intact. The stipe (stalk) should have a small length to thickness ratio. Stipe length should be sufficient to permit some trimming without cutting flush to the veil.

Quality Indices

Good quality, fresh '*Agaricus*' mushrooms should be white to dark brown. White forms are most prevalent. Uniform, well rounded cap with a smooth glossy surface and fully intact veil are indicators of best quality. Stipes are straight and glossy in appearance with an even cut edge. Cleanliness (minimal growth medium residue) and absence of browning or other discoloration are additional quality factors. Visible, open gills and absence of a stipe are negative factors.

U.S. grades are No. 1 and No. 2. Sizes range from Small {Button} (1.9 - 3.2cm / .75 - 1.25 in.), Medium (3.2 - 4.5cm / 1/25 - 1.75 in.), to Large (4.5 cm / 1.75 in. and larger) measured as cap diameter. Grades discriminate for maturity, shape uniformity, cleanliness and trim quality.

Optimum Temperature

0° - 1.5°C (32° - 35°F) Storage life is typically 5-7 days at 1.5°C(35°F) and 2 days at 4.5°C (40°F).

Optimum Relative Humidity

95-98 %; High relative humidity is essential to prevent desiccation and loss of glossiness. Drying is correlated with blackening of the stipe and gills and curling of the cap. Commonly mushrooms are packed and shipped in cartons with a perforated overwrap to maintain high humidity.

Rates of Respiration

Respiratory Quotient = $\frac{[CO_2]}{[O_2]}$

Temperature °C	°F	ml CO_2/kg·hr
0	32	14-22
5	41	35
10	50	50
15	59	NA
20	68	132-158
25	77	NA

Since RQ=1 ⇒ O_2 RR equivalent to CO_2 RR

To calculate heat production multiply ml CO_2/kg·hr by 440 to get Btu/ton/day or by 122 to get kcal/metric ton/day. NA= not applicable

Rates of Ethylene Production

>0.1µl / kg·hr at 20°C (68°F)

Responses to Ethylene

Agaricus mushrooms are not significantly impacted by exogenous ethylene.

Responses to Controlled Atmospheres(CA)

Extended storage (~12-15 days) in 3% O_2 and 10% CO_2 at 0°C has been Controlled demonstrated. Elevated CO_2 at 10-15 % (typically 10%) in air is beneficial in Atmosphere (CA) preventing decay and reducing the rate of blackening of the stipe and gills. The beneficial effect is most pronounced if temperatures cannot be maintained below 5°C (41°F). Short exposure to higher CO_2 concentrations (20 %) is safe and beneficial only if temperatures can be maintained at 0° - 1°C (32° - 34°F).

Improper control of controlled atmospheres or improper packaging can rapidly lead to depletion of oxygen resulting in conditions favorable for *Clostridium botulinum*. For this reason, primarily, the use of CA and MA is not common.

Physiological & Physical Disorders

Mushrooms will continue to develop after harvest which is why low & Physical temperature postharvest management is critical. Common disorders include Disorders upward bending of caps and **opening of the veil**.

Mushrooms are easily **bruised** by rough handling and develop patches of browning discoloration.

Freezing injury (water-soaked appearance leading to extreme softening) will likely result at temperatures of -0.6°C (30.9°F) or lower.

Signs of **CO_2 injury** are blackening and pitting.

Pathological Disorders

Disease is generally not an important source of postharvest loss in comparison with physiological senescence and improper handling or bruising. Diseases, such as Bacterial Blotch, and spoilage due to other

Pseudomonas spp. are generally eliminated during the harvest or sorting phases although development of patches of decay can occur with elevated temperature or extended storage.

Special Considerations

Rapid forced-air cooling soon after harvest is strongly recommended. Center-loading during shipment promotes good cooling-air circulation necessary for this commodity. Good arrival following surface transportation is enhanced when trailers are equipped with 'air-shocks' suspension. *Agaricus* mushrooms are reported to acquire strong odors, such as onion, in mixed loads or short term storage.

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Produce/ProduceFacts/Veg/mushroom.shtml updated June 10, 2002

THE WILEY ENCYCLOPEDIA OF PACKAGING TECHNOLOGY

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1984

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ket (see Films, stretch). It features good stretch and outstanding tack and optics and is offered in thicknesses of 0.65–2.0 mil (16.5–51 µm). As textile and rug-roll overwraps, they provide both shipment protection and merchandise visibility. When formulated with weather-resistant plasticizers and uv screens, they provide very good outdoor weatherability, and pigmented versions conceal tempting merchandise.

One of the newest applications for oriented flexible PVC is in the bundling of multiple aseptic packages (see Aseptic packaging). Ranging in thickness 0.75–1.50 mil (19–38 µm), this film provides a relatively high shrink at low temperatures, resulting in a firm, unitized pack. PVC seals easily, offers good economics, and merchandising appeal. Heavy-gauge (2.0–7.5 mil or 51–191 µm) flexible PVC has been used as a component of windowed cards for about 20 years. Toughness, formability, good dielectric sealability, and merchandising appeal are important qualities. Hardware and electrical items, flashlights, and automobile parts are typically packaged this way.

An interesting nonpackaging application is the use of high-clarity, glossy flexible PVC films as laminating films for paperback book covers. The combination of low cost, flexibility (resists cold crack) and adaptability to the Trio-Bond laminator (uses water-based adhesives, no solvents or heat) have made PVC competitive with acetates and lacquer coatings.

Physical Properties

Not surprisingly, of all the PVC additives, the type and level of plasticizer used in a flexible PVC film exercises the most influence over its physical properties. Its most obvious effect is on modulus (stiffness). PVC film can be stiff, like cellophane; but by simply adding plasticizer, one can produce a film that is nearly elastomeric. Some plasticizers are more efficient than others, which means that one can use less of a more efficient plasticizer to achieve a specific modulus reduction. A discussion of the selection process for some specific flexible PVC-film applications and the resultant film properties is germane to packaging applications.

Flexible PVC film to be used as a wrap for fresh red meat must offer good stretch characteristics (low modulus), high oxygen permeability, moderately low water vapor transmission rate (WVTR), good low temperature properties, heat sealability, and resilience. It must also be very transparent, glossy, and reasonably priced, and it must be manufactured from FDA-sanctioned raw materials. The first plasticizer to

Table 2. Properties of 1-mil (25.4 µm) Flexible PVC Film

Property	ASTM test		Flexible PVC meat package stretch type	Flexible PVC dispenser film	Flexible PVC shrink bundle film
specific gravity	D 1505		1.23	1.27	1.3
yield, in.²/(lb·mil) [m²/kg·mm)]			22,400 [1,254]	21,600 [1210]	21,400 [1198]
haze, %	D 1003		1.2	1.0	2.5
light transmission, %			>90	>90	>90
tensile strength, psi (MPa)	D 882	MD	5,000 (34.5)	5,500 (37.9)	18,000 (124)
		XD	4,500 (31)	5,500 (37.9)	5,500 (37.9)
elongation, %	D 882	MD	275	300	90
		XD	375	325	275
tear strength, gf/mil (N/mm) initial propagating	D 1922	MD	300 (116)	325 (125)	335 (129)
		XD	450 (174)	500 (193)	575 (222)
water absorption, 24 h, %	D 570		0	0	0
change in linear dimensions at 212°F (100°C) for 30 min, %	D 1204	MD	na	na	45
		XD			10
service temperature °F (°C), range			−20–150 (−29–66)	0–150 (−18–66)	10–150 (−12–66)
heat-seal temperature °F (°C), range			290–320 (143–160)	290–340 (143–171)	280–330 (138–166)
oxygen permeability cm^3·mil/(100 in.²·d·atm)[cm^3·µm/(m²·d·kPa)], 73°F (23°C), 50%rh 23C, 50% rh	D 1434		860 [3342] = 13,300 cc/m² day atm	340 [1321]	na
water vapor transmission rate: g.mil/(100 in.²·d) [g·mm/(m²·d)], 100°F (38°C), 90% rh			16 [6.3]	10 [3.9]	na
COF, face-to-face	D 1894				0.2
back-to-back			1.0	1.0	0.2
test conditions: 73°F (23°C), 50% rh					